

REMARKS

In the Office Action, the Examiner rejected claims 2-4 and 15-24 under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement; rejected claim 1 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,347,274 to Hassett; and rejected claims 2-24 under 35 U.S.C. § 103(a) as unpatentable over "Hospitals Use Alternatives to Off-Site Methods," Barlow, Rick Dana, Hospital Material Management, Ann Arbor, August 1992, Vol. 17, issue 8, page 14, 4 pages (hereinafter Stericycle) in view of U.S. Patent No. 7,035,856 to Morimoto and Hassett.

By this amendment, Applicant amends claims 1 and 15 to more clearly define the features of those claims.

Claims 1-24 are currently pending.

The Examiner rejected claims 2-4 and 15-24 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Applicant respectfully traverses this rejection.

The Examiner alleges that the specification does not disclose "monitoring the return of the first container from the waste treatment facility to the waste generating facility with the wireless tracking device." Office Action, page 2. Applicant respectfully disagrees for at least the reason that this feature was "disclosed" in the original disclosure. Moreover, the specification does indeed provide an enabling disclosure to a skilled artisan. For example, paragraph 12 states:

The present inventors have determined that by using a wireless tracking system, a method of tracking medical and industrial waste can be implemented that is both cost effective and easy to enforce. In short, by supplying waste generators with containers having a wireless tracking device attached, it is possible to dynamically track the movement of untreated waste to a treatment facility. In one preferred embodiment of the invention, individuals with handheld

readers scan the tracking device at various points along the disposal route. The information can then be upload from the handheld reader to a central monitoring station. In another preferred embodiment, the tracking is accomplished by use of GPS technology. When the waste is destroyed, the operator of the waste treatment facility can send a signal to the monitor to indicate the destruction. Optionally, an invoice may be generated and the customer billed. Additionally, the treated waste may be placed in a second container having a wireless tracking device attached and the movement of the treated waste tracked until its final disposition.

Moreover, the specification at paragraph 0027 states:

The wireless tracking system 100 also includes a tracking station 130. The tracking station 130 is equipped with a computer system (not shown) that stores tracking information as the waste disposal containers 160 are shipped from a waste generator 110 to a waste treatment facility 140 . In this embodiment, an operator reads tracking information from the tracking device using a handheld reader (not shown) and downloads the information to the computer at the monitoring station 130 . The downloading may be done over the phone lines or through a wireless communications network. Additionally, the movement of the waste disposal containers 160 may also be monitored as they are shipped from the waste treatment facility 140 to a final destination 150 for the waste. Readings with a handheld reader may be taken at each step in this process and the computer log updated throughout the delivery from the initial pickup at the waste generator 110 to the final destination 150 .

Regarding claim 15, the Examiner alleges that there is “no teaching of how to calculate an amount of what is owed based on a type of medical waste and a weight of the medical waste,” and such calculation would require “undue experimentation.” Office Action, page 2. Applicants disagree because on its face the Examiner’s statement belies his position. Moreover, the mere recitation of the claim given the disclosure enables the claimed feature. Nonetheless, Applicant submit that the specification does provide an enabling disclosure (see, e.g., para. 0032) and would not require undue experimentation, which one of ordinary skill would recognize to be the case.

Moreover, Applicant submits that the Examiner's rejection under section 112 for enablement is inapposite to M.P.E.P. 2164.01(a), which requires the Examiner to provide factual support for his position regarding undue experimentation.

2164.01(a) Undue Experimentation Factors

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In *re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (reversing the PTO's determination that claims directed to methods for detection of hepatitis B surface antigens did not satisfy the enablement requirement). In *Wands*, the court noted that there was no disagreement as to the facts, but merely a disagreement as to the interpretation of the data and the conclusion to be made from the facts. In *re Wands*, 858 F.2d at 736-40, 8 USPQ2d at 1403-07. The Court held that the specification was enabling with respect to the claims at issue and found that "there was considerable direction and guidance" in the specification; there was "a high level of skill in the art at the time the application was filed;" and "all of the methods needed to practice the invention were well known." 858 F.2d at 740, 8 USPQ2d at 1406. After considering all the factors related to the enablement issue, the court concluded that "it would not require undue experimentation to obtain antibodies needed to practice the claimed invention." *Id.*, 8 USPQ2d at 1407.

It is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors while ignoring one or more of the others. The examiner's analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole. 858 F.2d at 737, 740, 8 USPQ2d at 1404, 1407.

In view of the foregoing, the rejection of claims 2-4 and 15-24 under 35 U.S.C. § 112, first paragraph, should be withdrawn.

The Examiner rejected claim 1 under 35 U.S.C. § 102(b) as anticipated by Hassett. Applicant respectfully traverses this rejection.

Claim 1, as amended, recites the following feature: "monitoring a movement of a first container including untreated medical waste, the first container having a wireless tracking device attached thereto, the wireless tracking device configured with a global positioning system to allow tracking from a waste generating facility to a waste treatment facility using the wireless tracking device."

In contrast to claim 1, Hassett discloses a mobile, vehicle-borne radio transceiver unit, a series of portable and/or fixed base station transceiver units located at dispatch centers, check points and elsewhere along transit routes, and a data management network which bidirectionally communicates, through the base stations, with the mobile units, such that the mobile units may be portable, such that a driver of a vehicle carrying or pulling a hazardous material container can place it on the dashboard of the vehicle, or it may be permanently affixed either to the vehicle, or to a specific hazardous material container, such as a rail container, tank trailer or intermodal shipping container."

However, nowhere does Hassett disclose tracking medical waste, much less using GPS to perform the tracking. As such, Hassett fails to disclose or suggest at least the following feature of claim 1: "monitoring a movement of a first container including untreated medical waste, the first container having a wireless tracking device attached thereto, the wireless tracking device configured with a global positioning system to allow tracking from a waste generating facility to a waste treatment facility using the wireless tracking device," and claim 1 is thus not anticipated by Hassett. Therefore, the rejection of

claim 1 under 35 U.S.C. § 102(b) should be withdrawn.

The Examiner rejected claims 2-24 under 35 U.S.C. § 103(a) as unpatentable over Stericycle in view of Morimoto and Hassett. Applicant respectfully traverses this rejection.

Claims 214 each depend from claim 1 and includes all the features recited therein including, among other things, "monitoring a movement of a first container including untreated medical waste, the first container having a wireless tracking device attached thereto, the wireless tracking device configured with a global positioning system to allow tracking from a waste generating facility to a waste treatment facility using the wireless tracking device." As noted above, Hassett fails to disclose or suggest this feature.

Stericycle, at best, discloses that hospitals have medical waste, which is processed either on-site or off-site. However, nowhere does Stericycle disclose tracking medical waste, much less using GPS to perform the tracking. Moreover, although Morimoto discloses tracking and routing shipped items, it, like Hassett is silent with respect to tracking medical waste. Therefore, claims 2-14 are allowable over Hassett, Morimoto, and Stericycle, whether taken alone or in combination, and the rejection of claims 2-14 under 35 U.S.C. § 103(a) should be withdrawn.

Claim 15, although of different scope, includes features that are similar to the features noted above with respect to claim 1. For at least the reason given above with respect to claim 1, claim 15 is allowable over Hassett, Morimoto , and Stericycle, whether taken alone or in combination, and thus the rejection under 35 U.S.C. § 103(a) of claim 15 as well as claims 16-22, at least by reason of their dependency from impendent claim 15, should be withdrawn.

Moreover, regarding the motivation to combine, M.P.E.P. 2143.01 states "[i]f proposed modification would render the prior art invention being modified

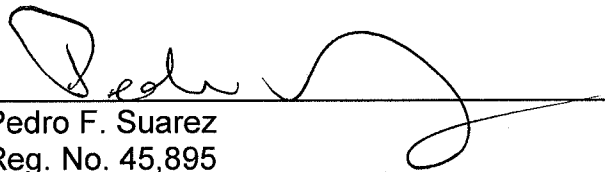
unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984, emphasis added).“ Applicant submits that one of ordinary skill in the art would not be motivated to make the Stericycle-Morimoto-Hassett combination proposed by the Examiner because the proposed three-way modification would make Morimoto unsuitable for its intended purpose. Specifically, the very purpose of Morimoto, as described in the Summary of the Invention, is to solve the problems of shippers, such as “express carriers (e.g., Federal Express, Airborne, DHL) and national postal services (e.g., the United States Postal Service and United Parcel Service).” To perform the modifications proposed by the Examiner would defeat the very purpose of Morimoto as medical waste would clearly not be hauled within those mechanisms. Therefore, the rejection of claims 2-24 under 35 U.S.C. §103(a) as unpatentable over Stericycle, Morimoto, and Hassett should be withdrawn for this additional reason.

CONCLUSION

It is believed that all of the pending claims have been addressed in this paper. However, failure to address a specific rejection, issue or comment, does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above are not intended to be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

Applicant is concurrently filing herewith a Petition for a two-month extension of time with the requisite fee. Authorization for a credit-card payment of the filing fees mentioned above is submitted herewith. No additional fees are believed to be due, however the Commissioner is authorized to charge any additional fees or credit overpayments to Deposit Account No. 50-0311, reference No. 36707-502. If there are any questions regarding this reply, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,



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